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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/993,696	12/18/1997	DAVID J. SCHANZLIN	251692002821	5525

7590

09/01/2004

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EXAMINER

WILLSE, DAVID H

ART UNIT PAPER NUMBER

3738

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

08/993,696

Applicant(s)

SCHANZLIN ET AL.

Examiner

Dave Willse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 68-103 is/are pending in the application.
- 4a) Of the above claim(s) 68-85 and 94-103 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 86-93 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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Claims 68-85 and 94-103 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group or species, there being no allowable generic or linking claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 86-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herrick, US 4,781,187, which employs donor corneal tissue (inherently comprising natural polymers such as collagen and mucopolysaccharide) as the implant material (column 3, lines 41-49). Substituting a synthetic polymer material would have been obvious in order to provide greater control over

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material properties, to reduce the risk of disease transmission, to ensure availability of materials, and so on, especially in the absence of any advantage or criticality in the instant disclosure of synthetic polymers over natural polymers (*In re Kuhle*, 188 USPQ 9; *Ex parte Clapp*, 227 USPQ 972, 973). In fact, the Applicant's specification states that synthetic or natural polymers may be used (page 1, lines 18-19; page 17, lines 15-17) and even includes collagen as a possible material (original claim 63). And synthetic polymers were well known in the art, as evidenced by the Applicant's statements at page 2, line 24 et seq. of the specification and by prior art references of record. Regarding claims 88 and 89, a radius of curvature within the prescribed ranges would have been immediately obvious from the intended use of the device, as best illustrated by Figures 3, 4, 7, and 9. Regarding claims 91-93, although Herrick specifies typical dimensions "on the order of a length of 3.5 to 4.0 millimeters" (column 3, lines 52-56), lengths as low as 2.0 millimeters would have been obvious in order to accommodate experimentation or practice on rabbits and other small animals or to minimize the length of the corneal incision.

Claims 86-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonchar et al., "Interlayer Refraction Tunnel Keratoplasty in Correcting Myopia and Astigmatism". The implants being of a synthetic polymer would have been an obvious material variant for reasons provided above with respect to the Herrick patent. Regarding claims 88 and 89, values within the specified ranges would have been immediately obvious from the purpose of the implants (Figure 3). Regarding claims 91-92: page 4, line 16, of the English translation. Regarding claim 93, an implant having a length of 2.0 mm or less would have been obvious in order to accommodate a variety of eye sizes (e.g., page 2, lines 3-4, of said translation) and refractive disorders.

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Claims 86, 87, and 90 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Civerchia, US 5,213,720. Regarding the last two lines of claim 86, MPEP 2106, section II. C., explains that language which suggests or makes optional but “does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation”; “examples of language that may raise a question as to the limiting effect of the language in a claim” are “adapted to” and “adapted for” clauses. The embodiments shown in Figures 14 and 17 can be inserted into the cornea (Figure 4; column 6, lines 20-21; column 18, lines 9-12) and thus possess a radius of curvature along a centroidal axis of at least 5.0 mm; because of their elongate form, these embodiments clearly extend in a meridional direction.

Claims 88, 89, and 91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Civerchia, US 5,213,720. Regarding claims 88 and 89, the particular radius of curvature would have been immediately obvious from the anatomy depicted in Figure 4. Regarding claims 91-93, the length of the tabs 132 being less than or equal to 2.0 mm would have been obvious from the drawing (Figure 17) and would have been obvious in order to lessen the trauma to the cornea.

The Applicant's remarks have been reviewed. In regard to the Herrick patent and the Gonchar et al. article, the Applicant states that “it was not an obvious variation to substitute a polymer for a natural material” (e.g., page 11, lines 4-5, of the Applicant's Response received on April 21, 2004) but does not offer any support for such assertion. As for the Civerchia patent, the Applicant's arguments do not address the “insert” embodiments referenced by the previous Office action (mailed on October 20, 2003).

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is (703) 308-2903. The examiner can normally be reached Monday through Thursday and often on Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



**Dave Willse**  
**Primary Examiner**  
**Art Unit 3738**